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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/627,247	07/25/2003	Sean D. Monahan	Mirus.007.01.2	4188
25032	7590	06/23/2005	EXAMINER	
MIRUS CORPORATION 505 SOUTH ROSA RD MADISON, WI 53719			GUZO, DAVID	
			ART UNIT	PAPER NUMBER
			1636	

DATE MAILED: 06/23/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/627,247

Applicant(s)

MONAHAN ET AL.

Examiner

David Guzo

Art Unit

1636

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 4/8/05.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 14-26 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 14-26 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 01 December 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date: _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date: _____ | 6) <input type="checkbox"/> Other: _____ |

Detailed Action

Priority

Applicant's have amended the Continuing Data on page 1 of the Specification to claim benefit to the parent applications 10/081,461, filed 2/21/2002, and 09/354,957, filed 7/16/1999 as well as provisional application 60/093,321, filed 7/17/1998. While applicants recite priority claims to the 10/081,461 and 09/354,957 applications in the transmittal papers and the specification, as filed, applicants have not previously claimed benefit for the 60/093,321 application. Benefit under 35 USC 120 is granted for the 10/081,461 and 09/354,321 applications but benefit under 35 USC 119(e) is not granted for the 60/093,321 application because the benefit claim was not timely filed. The benefit claim must be cancelled in the absence of a grantable petition to accept an unintentionally delayed benefit claim under 35 U.S.C. 119(e), 120, 121 and 365(c).

It is noted that this application appears to claim subject matter disclosed in prior Application No. 60/093,321, filed 7/17/1998. A reference to the prior application must be inserted as the first sentence(s) of the specification of this application or in an application data sheet (37 CFR 1.76), if applicant intends to rely on the filing date of the prior application under 35 U.S.C. 119(e) or 120. See 37 CFR 1.78(a). For benefit claims under 35 U.S.C. 120, the reference must include the relationship (i.e., continuation, divisional, or continuation-in-part) of all nonprovisional applications. Also, the current status of all nonprovisional parent applications referenced should be included.

If the application is a utility or plant application filed under 35 U.S.C. 111(a) on or after November 29, 2000, the specific reference to the prior application must be submitted during the pendency of the application and within the later of four months from the actual filing date of the application or sixteen months from the filing date of the prior application. If the application is a utility or plant application which entered the national stage from an international application filed on or after November 29, 2000, after compliance with 35 U.S.C. 371, the specific reference must be submitted during the pendency of the application and within the later of four months from the date on which the national stage commenced under 35 U.S.C. 371(b) or (f) or sixteen months from the filing date of the prior application. See 37 CFR 1.78(a)(2)(ii) and (a)(5)(ii). This time period is not extendable and a failure to submit the reference required by 35 U.S.C. 119(e) and/or 120, where applicable, within this time period is considered a waiver of any benefit of such prior application(s) under 35 U.S.C. 119(e), 120, 121 and 365(c). A benefit claim filed after the required time period may be accepted if it is accompanied by a grantable petition to accept an unintentionally delayed benefit claim under 35 U.S.C. 119(e), 120, 121 and 365(c). The petition must be accompanied by (1) the reference required by 35 U.S.C. 120 or 119(e) and 37 CFR 1.78(a)(2) or (a)(5) to the prior application (unless previously submitted), (2) a surcharge under 37 CFR 1.17(t), and (3) a statement that the entire delay between the date the claim was due under 37 CFR 1.78(a)(2) or (a)(5) and the date the claim was filed was unintentional. The Director may require additional information where there is a question whether the delay was

unintentional. The petition should be addressed to: Mail Stop Petition, Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450.

35 USC 102 Rejections

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 14-19 and 23-26 stand rejected under 35 U.S.C. 102(b) as being anticipated by Bolcsak et al.

This rejection is maintained for reasons of record in the previous Office Action (mailed 9/8/04) and for reasons outlined below.

Applicants have responded to this rejection by amending the claims to recite “a biologically labile surfactant” as part of the reverse micelle. Applicants argue that the bonds recited by Bolcsak et al. are not labile under physiological conditions and are very stable. It is noted that applicants define a “biologically labile surfactant” on page 17 of the instant specification:

The present invention also relates to a method in which a biologically active compound is delivered to a cell comprising a step in which the biologically active compound is mixed with a biologically-labile surfactant. A biologically-labile surfactant is a surfactant in which the hydrophobic moiety is cleaved from the hydrophilic moiety by cellular processes or its surfactant properties are rendered inactive within the cell, tissue or organism. Examples include surfactants that contain disulfide bonds that are labile within the cell, tissue, or organism.

Applicant's arguments filed 4/8/05 have been fully considered but they are not persuasive. Applicants are incorrect in stating that the bonds in the amphipathic molecules disclosed by Bolcsak et al. are not labile under physiological conditions. For example, Bolcsak et al. recite that the amphipathic surfactant can have a chemical bridge between the hydrophilic and hydrophobic moieties wherein the bridge can be a disulfide bond (one of the types of bonds which applicants indicate is a biologically labile bond) (see Bolcsak et al., column 5, lines 5-41 and column 10, lines 24-59). Bolcsak et al. also recite that the bonds linking the hydrophilic and hydrophobic moieties of the molecule can be other bonds (such as thioester, sulfonate, amine, etc.) which can also be labile under biological (physiological) conditions given the numerous enzymes and biologically active molecules which are present in eukaryotic cells and can attack the types of bonds recited by Bolcsak et al. With regard to applicants citation of the portions of the Bolcsak et al. patent which refer to stable bonds, it is noted that all the sections of the patent referred to by applicants cite specific preferred embodiments wherein the bonds linking the hydrophilic and hydrophobic moieties could be bonds which would promote the stability of the molecules **during storage**. The sections of the Bolcsak et al. patent referred to by applicants do not recite the stability of the bonds under conditions very different from simple storage conditions, i.e. physiological conditions. It must therefore be considered that Bolcsak et al. teaches the claimed invention.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 20-22 stand rejected under 35 U.S.C. 102(e) as being anticipated by Grinstaff et al.

This rejection is maintained for reasons of record in the previous Office Action and for reasons outlined below.

Applicants traverse this rejection by asserting that the instant invention is disclosed in US 6,429,200 (hereafter the '200 patent), for which applicants claim priority and which has an earlier effective filing date than the 102(e) date of Grinstaff et al.

Applicants arguments have been considered but are not persuasive. The '200 patent does not disclose the claimed invention. The '200 patent does not disclose a process for forming a complex deliverable to a cell wherein an amphipathic molecule in the complex contains a silicon-heteroatom bond. The portions of the '200 patent which applicants assert provide support for the claimed invention do not recite an amphipathic molecule with a silicon-heteroatom bond.

With regard to the claimed process wherein at least one of the amphipathic molecules consists of a biologically labile surfactant, it is noted that Grinstaff et al. recites linkers linking the hydrophobic and hydrophilic moieties wherein the linkers can

Art Unit: 1636

be an amide, amine, carbonate, sulfate, phosphate, etc. group and can be chosen from naturally occurring groups such as the three carbon glycerol group with an amide substituted as a linker, etc. (see paragraphs [0065] and [0070]. It must be considered, absent evidence to the contrary, that these groups, derived from naturally occurring ceramides, phospholipids, etc., would contain one or more bonds that would be cleavable under physiological or biological conditions.

Any rejection not repeated in this Office Action is withdrawn.

The Terminal Disclaimers filed 12/1/04 have been approved.

The new Drawing filed 12/1/04 is approved.

No Claims are allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).


A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Guzo, Ph.D., whose telephone number is (571) 272-0767. The examiner can normally be reached on Monday-Thursday from 8:00 AM to 5:30 PM. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Irem Yucel, Ph.D., can be reached on (571) 272-0781. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

David Guzo
June 16, 2005


DAVID GUZO
PRIMARY EXAMINER